UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,742	03/05/2002	James H. Anderson	56,492 (71699)	8190

21874 7590 12/08/2003

EDWARDS & ANGELL, LLP
P.O. BOX 9169
BOSTON, MA 02209

EXAMINER	
ASHBURN, STEVEN L	
ART UNIT	**PAPER NUMBER**
3714	

DATE MAILED: 12/08/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,742	ANDERSON ET AL.	
	Examiner	Art Unit	
	Steven Ashburn	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) *38-43,45 and 64-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37,46-63,74 and 75* is/are rejected.

7)☒ Claim(s) *44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Claims 38-43, 45 and 64-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in applicant's response dated (August 27, 2003 (paper no. 16). The requirement is still deemed proper and is therefore made FINAL. The examiner's response to the applicant's traversal of the restriction requirement is provided below in the "Response to Arguments" section of this action. A complete reply to any final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is insufficient antecedent basis for the limitations in the claim because the claim is dependant upon itself. For the purposes of examination, the examiner assumes claim 8 is dependant on claim 7.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, 10, 16-23, 25, 28, 33-35, 37, 47, 48, 52-55, 57, 58, 61, 62 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by Chosack et al., WO 99/38141 (July, 29, 1999).

Chosack discloses a system for simulating a medical procedure performed on a subject, featuring: a simulated organ; a simulated instrument for performing the medical procedure on the simulated organ; a locator for determining a location of the simulated instrument within the simulated organ, and a visual display for displaying images from the medical procedure, such that the images simulate visual data received during the medical procedure as performed on an actual subject, the visual display including: a three-dimensional model of the simulated organ, the model being divided into a plurality of segments; a loader for selecting at least one of the plurality of segments for display, the at least one of the plurality of segments being selected according to the location of the simulated instrument within the simulated organ controller for selecting each image from the selected segment according to the location of the simulated instrument; and a displayer for displaying the image according to the controller. *See abstract.*

Regarding independent claims 1 and 75: Chosack teaches

a. A medical device comprising a first end for manipulation by a user and a portion comprising a second end insertable into a simulated body cavity or body lumen in a manikin. *See fig. 1, 5(a); p. 10:4-14; 21-3-17.*

b. A manikin comprising an interface for receiving the second end and for interfacing with a simulated body cavity or lumen within the manikin. *See id.*

c. Interface comprising a directional force feedback mechanism for exerting direction force on the medical device in response to a feedback signal received by the force feedback mechanism. *See id.*

d. System model interaction between the device and the body cavity or lumen three dimensionally in real-time. *See p. 10:23-29; 13:30-14:27.*

Regarding claims 2 and 52: *Chosack* additionally teaches having the directional force feedback system provide resistance to forward motion but enable free reverse motion in response to the feedback signal. *See p. 19:3-11, 21:32-22:7, 25:13-26:2.* More specifically, the instrument would provide resistance to forward motion if the simulated device is driven into the intestinal wall but provide free reverse motion when pulled back from the wall.

Regarding claim 3: *Chosack* additionally teaches the directional force feedback mechanism comprising a rolling element coupled to the second end and an internal surface of the simulated body cavity or lumen comprising an oblique slot for receiving the rolling element. *See fig. 7(a)-(d); p. 24:16-25:2.*

Regarding claim 4: Chosack additionally teaches, in response to a feedback signal, forward movement of the second end causes the rolling element to be received by the slot thereby causing resistance to forward motion. *See id.*

Regarding claim 5: Chosack additionally teaches a motor controlling the movement of the rolling element. *See p. 25:13-21.*

Regarding claim 6: Chosack additionally teaches a tactile feedback mechanism. *See id.*

Regarding claim 9: Chosack additionally teaches continuously tracking the second end of the medical device. *See p. 6:19-22, 12:15-21.*

Regarding claim 10: Chosack additionally teaches an encoder for tracking the translation of the device and an encoder for tracking the rotation of the device. *See p. 10:31-11:1, 21:18-28.*

Regarding claim 11: Chosack additionally teaches a tracking unit comprising a light source, a signal processing circuit and one or more optical sensors, wherein the tracking unit is placed within the interface in optical communication with the device when it is inserted in the cavity or lumen. *See fig. 9(a)-(d); 28:18-29:2.* More specifically, when the device is inserted in the manikin, various tools can be inserted into the device, wherein the tools are tracked with optical sensors. *See id.*

Regarding claim 16: *Chosack* teaches one or more additionally medical devices comprising a first end for manipulation by a user and a portion comprising a second end for insertion into the simulated body cavity are inserted into the interface, and wherein the position of each medical device is independently monitored. *See fig. 9(a)-(e); p. 28:1-29:2.*

Regarding claims 17, 37 and 61: *Chosack* teaches various medical devices including endoscopes, forceps and coils. *See id.* The remaining devices are admitted equivlants.

Regarding claim 18: Chosack additionally teaches a system comprised of a table for placing a manikin and a processor connectable to a network. *See fig. 1, 3B(80).*

Regarding claims 19: Chosack additionally teaches the system has at least one user device connected to the network and the device comprising a selectable display interface for displaying a three-dimensional representation of a simulated body cavity of a patient. *See id.*

Regarding claim 20: Chosack additionally teaches a first display interface displaying a three dimensional representation of a medical device corresponding to a medical device which is interfaced with the manikin and wherein the system simulates on the display the movement of the medical device within the simulated body cavity of the manikin in real-time when the user manipulates the medical device interfaced with the manikin. *See fig. 2-3(a); p. 12:5-14, 7:19-25, 10:23-29.*

Regarding claim 21: Chosack additionally discloses a simulated scanning display for displaying a two-dimensional image of a simulated body cavity. *See p. 7:4-15.*

Regarding claim 22: Chosack additionally discloses a simulated scanning display being part of a simulated scanning device. *See p. 7:16-18, 14:8-20.*

Regarding claim 23: Chosack additionally discloses a simulated scanning device being an x-ray imaging system. *See id.*

Regarding claim 25: Chosack additionally discloses a re-configurable control panel for performing image acquisition selection, image display. *See fig. 2, 3(42); p. 12:5-32.*

Regarding claim 28: *Chosack* discloses the system is connectable to a database of patient images or medical data. *See fig. 2, 3(42); p. 12:5-32.*

Regarding claim 30: *Chosack* discloses patient images of a body cavity from a patient affected by a pathology. *See id.*

Regarding claim 33: *Chosack* discloses displaying an image or medical data on a user display in response to accessing the data. *See fig. 2, 3(42); p. 12:5-32.*

Regarding claims 34 and 35: *Chosack* discloses a user display interface providing access to the database and wherein, in response to accessing it, the system displays an image and/or medical data on the display. *See id.*

Regarding claim 47: *Chosack* discloses simulating deformation of the body cavity by the medical device. *See p. 13:6-13, 16:2-19.*

Regarding claim 48: *Chosack* discloses a system simulating an operation of a medical device for a variety of procedures including surgical procedures. *See p. 28:1-7, 29:19-27.*

Regarding claim 53: *Chosack* discloses a processor in communication with the directional force-feedback mechanism, the processor connectable to a network; a first user dive in communication with the processor, the first user device comprising a first display interface for displaying a representation of a body cavity; and for providing access to a database of three-dimensional images of body cavities and lumens from a plurality of different patients wherein the response to the selection, the representation is displayed on the first display interface. *See fig. 1, 2, 3A, 3B, 5A, 5B; 9. 9:29-11:5; 11:26-19:20.*

Regarding claim 54, *Chosack* discloses a first display interface a displays a three-dimensional representation of the medical device and wherein the system simulates the movement of the medical device within the body cavity or lumen in real-time as a first user manipulates the medical device which is interfaced with the manikin. *See id.*

Regarding claim 55: *Chosack* discloses a monitoring station comprising a second display interface in communication with the processor and the first display interface and wherein the second display interface provides a second user with access to the database. *See p. 19:12-20:12.*

Regarding claim 57: *Chosack* discloses simulating the deformation of a body cavity or lumen in response to movement of the medical device by the first user and displays the representation of the deformation on the first display interface. *See p. 16:2-31.*

Regarding claim 58: *Chosack* discloses performs an operation on the simulated body cavity or lumen and the first display interface displays a simulation of the operation. *See fig. 2.*

Regarding claim 62: *Chosack* discloses inserting one or more additional medical devices into the simulated body cavity or lumen, and the movement of each medical device is independently monitored. *See fig. 9A-9E; p. 28:1-29:2.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 8, 63 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Chosack* in view of Rosenberg et al., U.S. Patent 5,959,613 (Sep. 28, 1999).

Regarding claims 7, 63 and 74: *Chosack* teaches accurately replicating visual and tactile sensations of an endoscope during actual medical procedures. *See p. 11:12-16, 29:7-19.* Towards that end, it suggests that the system simulates effects such as the random vibration of tissue. *See p. 7:23-25, 13:25-29.* However, *Chosack* does not describe the feature of providing continuous vibrational feedback to a user holding the device. *Rosenberg* discloses an analogous system which for simulating medical devices such as endoscopes. *See col. 5:18-27, 11:18-34.* The system provides continuous vibrational feedback to the user. *See col. 14:30-64.* In view of *Rosenberg,* it would have been obvious to an artisan at the time of the invention to modify *Chosack,* wherein the system simulates vibration of tissues, to add the feature of continuous vibration feedback to a user holding a device. As suggested by *Rosenberg,* the modification would enhance the simulator by providing accurate and realistic tactile sensations to the user. *See col. 4:3-26.*

Regarding claim 8: *Chosack* describes a medical device wherein a unit on the device's second end provides tactile feedback. *Rosenberg* describe providing vibration with a continuously rotating motor. *See col. 9:53-64.* Hence, when the combination is taken as a whole, it suggests to an artisan at the time of the invention medical device simulator with a continuously rotating motor its second end providing vibrational feedback to increase the realism of the system.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Chosack* in view of *Belson* et al., U.S. 6,610,007 B2 (Aug. 26, 2003).

Regarding claim 12: *Chosack* does not describe light from a light source reflecting on the device when inserted and wherein the reflected light is received by one or more optical sensors. *Belson* discloses a method for tracking endoscopes whereby the scope's position is detected by reflecting on the device and

having the reflected light is received by one or more optical sensors. *See col. 13:3-21.* Hence it is known to track the position of endoscopes by detecting light reflect off the device. In view of *Belson*, it would have been obvious to modify *Chosack*, wherein the linear position of a device is tracked inside a manikin's body, to add the feature of tracking the device by describe light from a light source reflecting on the device when inserted and wherein the reflected light is received by one or more optical sensors because the method is equivalent known in the art for the same purpose of tracking linear position.

Regarding claim 13: *Chosack* additionally discloses simulating the movement of the device in real-time on the user display in response to detection of movement by position sensors. *See pp. 6:15-17:7:2.*

Regarding claim 14: *Chosack* describes tracking the Cartesian position (x, y, z) of the device. *See p. 21:18-31.* However neither *Chosack* nor *Belson* describe placing position sensors perpendicular to one another. Because position sensors typically sense one direction of movement, it common to position the sensors perpendicularly to allow them to sense position along each Cartesian axes. Hence, in the system suggested by the combination of *Chosack* in view of *Belson*, wherein the Cartesian position is tracked by reflected light sensors, it would have been obvious to an artisan to place the placing position sensors perpendicular to one another to capture to Cartesian position of the device.

Regarding claim 15: *Belson* additionally describes a tracking unit configured as a rail along which the device can move. *See fig. 3-5.*

Claims 24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chosack in view of Simon et al., U.S. Patent 6,470,207 B1 (October 22, 2002) and Saunders, U.S. Patent 6,572,376 B1 (Jun. 3, 2003).

Regarding claim 24: *Chosack* discloses all the features of the claim except a movable C-arm for a scanning device within scanning distance of the manikin. *Simon* discloses methods for performing endoscopic surgery wherein scanner is coupled to a C-arm within scanning distance of a patient. It is known in simulation system to increase the realism of the system by simulating actual devices and thereby provide more effective training. *See, e.g., Saunders, col. 1:47-52, 2:8-16.* Hence, in view of *Simon* and *Saunders*, it would have been obvious to an artisan at the time of the invention to modify medical device simulated disclosed by *Chosack*, wherein a scanning device is simulated, to add the feature of a movable C-arm for a scanning device within scanning distance of the manikin and thereby increase the realism and effectiveness of training.

Regarding claim 32: *Simon* describes using a foot pedal to activate the scanning device. *See col. 11:44-64.*

Claims 26, 27, 29 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Chosack* in view of Pollak et al., U.S. 6,106,297 (Aug. 22, 2000).

Regarding claim 26: *Chosack* teaches all features of the claims except a monitoring station comprising a second user interface device connectable to the network and comprising a second display interface for enabling a second user to monitor to movement of the medical device. Likewise, it is generally known in the field of simulation devices to provide interfaces allowing instructors and observers to monitor training. *See, e.g. Pollak, col. 1:17-24. Pollak* discloses an analogous training simulator

having a monitoring station comprising a second user interface device connectable to the network and comprising a second display interface for enabling a second user to monitor to movement of the device in a simulated scenario. *See fig. 2, 7, 8; col. 1:56-3:58.* One of ordinary skill in the art consider techniques from training simulations in other fields in medical training. *See, e.g., Issenberg et al., "Simulation Technology for Health Care Professional Skills Training and Assessment", JAMA, Vol. 282, No. 9, p. 2 (Sep. 1, 1999).* Hence, in view of *Pollak*, it would have been obvious to an artisan at the time of the invention to modify the *Chosack*, wherein a simulator is used for training users to operate a medical device within the simulated body cavity, to add the feature of a monitoring station comprising a second user interface device connectable to the network and comprising a second display interface for enabling a second user to monitor to movement of the medical device. As described by *Pollak*, the modification would enhance the device by giving an instructor a consistent and easy-to-use graphical interface to control and monitor a training scenario. *See col. 2:43-3:4.*

Regarding claims 27 and 56: *Pollak* additionally teaches a second display interface displaying selectable options enabling a second user to select or change parameters of the simulator and wherein the selection causes the three dimensional image of the simulated environment displayed to a first user to change or reflect the changed parameters. *See col. 3:9-13, 5:44-59.* Hence, when the prior art is taken as a whole, the combination of *Chosack* with *Pollak*, wherein the movement of a medical device inside a body cavity is simulated using a manikin, it suggests a second display interface displaying selectable options enabling a second user to select or change anatomical or physiological parameters of the simulated body cavity and wherein the selection causes the three dimensional image of the simulated body cavity displayed to a first user to change or reflect the changed parameters.

Regarding claim 29: *Chosack* discloses the system is connectable to a database of patient images or medical data. *See fig. 2(42); col. 12:5-36.*

Claims 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Chosack* in view of *Pollak*, as applied to claim 26 above, in further view of Hon, U.S. Patent 6,074,213 (Jun. 13, 2000).

The medical trainer suggested by the *Chosack* in view of *Pollak* describes all the features of the claim except enabling the first user display to display the information on the second user display. It is well known in training devices to allow users at different stations to selectively view the same image so that the users, instructors or observers interact on a common perspective. For example, *Hon* discloses an analogous training system which enables a first user display to display the information on the second user display. *See fig. 9, 14, 17.* It would have been obvious to an artisan at the time of the invention to modify the medical training simulator suggested by *Chosack* in view of *Pollak* and *Lapotang*, wherein an instructor/operator monitors the simulation from a second display station, to add the feature of enabling the first user display to display the information on the second user display to allow users at different stations to selectively view the same image so that the users, instructors or observers share a common perspective.

Claims 46, 49-51, 60 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Chosack* in view of Merril, U.S. Paten 6,106,301 (Aug. 22, 2000).

Regarding claims 46 and 59: *Chosack* discloses all the features of the claim except simulating the deployment of a balloon within the body cavity comprising a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon; a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device and an electrical pressure meter for reading

pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor. *Merril* discloses an analogous system for simulating minimally invasive procedures wherein the device simulates deployment of a balloon within the body cavity comprising a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon; a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device and an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor. *See fig 2; col. 7:1-11, 16:11-41.* In view of *Merril*, it would have been obvious to an artisan at the time of the invention to modify the medical device simulator disclosed by *Chosack* to add the features of simulating deployment of a balloon within the body cavity comprising a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon; a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device and an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor. As described by *Merril*, the modification would allow training in angioplasty and stent deployment procedures. *See id.*

Regarding claims 49, 50 and 51: *Merril* discloses simulating a minimally invasive procedure in blood vessels. *See col. 8:17-29.* It is within the implicit knowledge of an artisan that minimally invasive procedures are performed in the blood vessels of the brain and heart. Hence, it would have been obvious to an artisan at the time of the invention to modify the medical device simulate discloses by *Chosack*, wherein the device simulates a minimally invasive medical procedure, to add the feature of simulate the movement of devices through blood vessels in the brain and heart. As suggested by *Chosack,* the

modification would enhance the device by allowing users to gain skills necessary to perform procedures without requiring practice. *See col. 5:50-57*

Regarding claim 60: *Merril* discloses the operation being the injection of a radio-opaque fluid within the body cavity or lumen. *See col. 6:45-65.*

Allowable Subject Matter

Claims 44 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's election with traverse of Invention I in the Office Action dated July 25, 2003 (paper no. 13) is acknowledged. The traversal is based on the grounds that the applicant's amendment dated May 5, 2003 placed no additional burden on the examiner beyond the claims had been examined on their merits in the prior office action. The argument is not persuasive.

MPEP § 811 states:

> 37 CFR 1.142(a), second sentence states: "[i]f the distinctness and independence of the invention be clear, such requirement will be made before any action upon the merits; however, it may be made at any time before final action in the case at the discretion of the examiner." This means the examiner should make a proper requirement as early as possible in the prosecution, in the first action if possible, otherwise, as soon as the need for a proper requirement develops. Before making a restriction requirement after the first action on the merits, the examiner will consider whether there will be a serious burden if restriction is not required.

In this case, the application clearly includes four distinct inventions including (I) a system for providing tracking for simulated devices, (II) a system for simulating a syringe device, (III) to a system simulating a balloon-angioplasty device, and (IV) a system for simulating a coil embolization device. The examiner's reasons for the restriction requirement are detailed in Office Action dated July 25, 2004 (paper no. 13).

Restriction prior to first action on the merits would have been proper and preferable. Failing that, the examiner has made a requirement as soon as possible in the prosecution.

Additionally, the applicant's amendment dated May 6, 2003 (paper no. 11) added limitations that further distinguished the inventions and increased the burden of examination. For example, the amendment to Invention I added the feature of three-dimensionally modeling interactions between a device and a body cavity or lumen. This feature further distinguishes system for tracking simulated devices of Invention I from the simulated devices claimed in Inventions II-IV.

Regarding claims 64, 72 and 73, the applicant argues further that the claims should be rejoined because the applicant's amendment did not amend the claims and thereby increase the burden on the examiner. The argument is not persuasive because the claims as originally filed were drawn to distinct inventions.

Consequently, for the reasons given above, the requirement is still deemed proper and is therefore made FINAL.

Applicant's arguments with respect to claims 1-37, 44 and 46-63 have been considered but are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Ashburn whose telephone number is 703 305 3543. The examiner can normally be reached on Monday thru Friday, 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 703-308-1806. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Any

inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1148.

s.a.

S. THOMAS HUGHES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700